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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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EPA

Pesticide Fact Sheet

Name of Chemical: MANEB
Reason for Issuance: REGISTRATION STANDARD
Date Issued: October 3, 1988
Fact Sheet Number: 182

1. DESCRIPTION OF CHEMICAL

Chemical Name: Manganese ethylene bisdithiocarbamate

ANSI Common Name: Maneb

Principal Trade Names: Dithane M-22™, Manzate™

EPA (Shaughnessy) Code: 014505

Chemical Abstracts Service (CAS) Number: 12427-38-2

Year of Initial Registration: Late 1940's

Pesticide Type: Fungicide

Chemical Family: Ethylene bisdithiocarbamate (EBDC)

U.S. and Foreign Producers: Penwalt

2. USE PATTERNS AND FORMULATIONS

Registered uses: Terrestrial food crop (fruits, vegetables, seed crops, nuts, flax, and grains); terrestrial non-food crop (ornamentals, lawns, turf); greenhouse food (tomatoes, rhubarb) and non-food crop (ornamentals)

Predominant uses: Apples, potatoes, tomatoes and sweet corn

Pests controlled: Foliar fungal diseases of selected fruit, nut, vegetable, grain, field and ornamental (including turf) crops.

Types of Formulations:	Technical, formulation intermediate, dust, granular, wettable powder, wettable powder/ dust, flowable concentrate, and ready-to-use.
Types and Method of Application:	Foliar application to vegetable crops and apples by aerial equipment or ground equipment. Foliar treatment of tobacco or vegetable seed beds, application of sprays or dusts might be by means of hand held compressed air sprayers or dusting equipment. Potato and tomato foliage may be treated by means of solid set, wheel move, or center pivot sprinkler irrigation equipment.
Application Rates:	Terrestrial food crop: 0.01 - 8.4 lb. ai/A Terrestrial nonfood crop: 0.8 - 3.2 lb. ai/A Grenhouse food crop: 1.1 - 2.4 lb. ai/100 gal. Greenhouse nonfood crop: 0.8 - 2.4 lb. ai/100 gal.

3. SCIENCE FINDINGS

a. Chemical Characteristics

Physical state: Powder
Color: Yellow
Odor: faint
Molecular Formula: $(C_4H_6MnN_2S_4)x$

Toxicology Characteristics

Acute Oral: LD_{50} = 4,400 mg/kg bw (rat) (Toxicity Category III)

Acute Dermal: LD_{50} > 2 gm/kg bw (rabbit) (Toxicity Category III)

Acute Inhalation: LC_{50} > 2.22 $\pm$ 0.26 mg/l (rat); (Toxicity Category III)

Primary Dermal Irritation: Non-irritating (rabbit)(Toxicity Category IV)

Primary Eye Irritation: Severe eye irritant (rabbit)(Toxicity Category I)

Dermal Sensitization: Sensitizer (guinea pig)

Major Routes of Exposure: Oral, dermal and inhalation

Subchronic Toxicity: No observed effect level (NOEL) = 100 ppm,
LEL (increase in thyroid weight in males) = 300 ppm
(Monkeys).

Oncogenicity: Studies required

Chronic feeding: Studies required

Metabolism: Studies in rats indicate that maneb is hydrolyzed, readily absorbed and excreted in the urine and feces. The major metabolite is ETU.

Reproduction: Study required

Teratogenicity & Developmental Toxicity: Studies required

Mutagenicity: Mutagenicity testing showed that maneb was positive for inducing chromosomal damage in an in vitro SCE (sister chromatid exchange) assay with metabolic activation. Evidence showed that maneb is most likely not an initiating agent and the evidence on promotion capability was negative. Additional data are required before the unscheduled DNA synthesis (UDS) assay can be upgraded to acceptable status. The following studies were negative: Sister chromatid exchange in CHO cells in the absence of a metabolic activation and Host mediated assay in mice.

Physiological and Biochemical Characteristics

Metabolism and Persistence in Plants and Animals:

Metabolism of maneb is not completely understood. Additional data are being required in plants and livestock. ETU is a major metabolite of concern.

Environmental Characteristics

Maneb degrades to ETU and other transient degradates in water and soil. ETU is stable in water at pH 5-9 and under sunlight and the degradation of ETU on soil is not enhanced by sunlight radiation.

Maneb degrades very rapidly under anaerobic aquatic soil conditions but ETU is relatively stable under these conditions.

ETU is stable in water at pH 5-9 and under sunlight and the degradation of ETU on soil is not enhanced by sunlight radiation. ETU is the degradate of major environmental concern. There are indications that ETU may leach and enter groundwater. However, additional data are required to complete the groundwater assessment.

Ecological Characteristics

o Maneb has been found to be practically nontoxic to birds and mammals.

Avian dietary toxicity: LC_{50} > 9,000 ppm (bobwhite)

o The toxicity of a 80% product to warmwater fish is highly toxic.

4. TOLERANCE ASSESSMENT

Tolerances, expressed as zinc ethylene bisdithiocarbamate, have been established for residues of maneb in a variety of raw agricultural commodities (40 CFR 180.110).

The toxicology data for maneb are insufficient to determine an Acceptable Daily Intake (ADI) or whether the toxicity observed in the studies is due to maneb or ETU. A subchronic study has been used to calculate a Provisional ADI (PADI). Because a subchronic study was used, an uncertainty factor of 1000 was employed. The PADI for maneb is 0.0005 mg/kg/day based on the six month feeding study with a NOEL of 5 mg/kg/day.

The theoretical maximum residue contribution (TMRC), based on the assumption that 100 percent of each crop is treated and contains residues at the tolerance level, is 0.030 or approximately 600 percent of the PADI. Based on a more realistic dietary assessment, using anticipated field residues and estimate of percent crop treated, the estimated average consumption for the U.S. population is 0.0036 mg/kg/day or 70 percent of the PADI.

5. SUMMARY OF REGULATORY POSITIONS

The Agency has initiated a Special Review for maneb along with the other EBDC's in June 1987 because of concern about the oncogenic risk to consumers from dietary exposure to ETU from food treated with these pesticides, and the risks of teratogenicity and adverse thyroid effects to applicators and mixer/loaders from exposure to ETU.

- ETU has been classified as a B_2 oncogen (probable human carcinogen).

- The Agency will not consider establishment of new food use tolerances for maneb because the current residue chemistry and toxicology data are not sufficient to assess existing tolerances and the toxicology data base is insufficient to determine an ADI and also does not allow a decision as to whether observed toxicity is due to maneb or ETU.

- The Agency will consider the need for establishment of tolerances for ETU and any intermediate metabolites when data are sufficient to permit such decisions.

- The Agency will not establish any food/feed additive regulations pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) and is deferring action on previously established food/feed additive regulations.

- Protective clothing labeling for maneb products, as specified as a result of the 1982 Decision Document should be updated.

- The Agency is requiring reentry data for maneb. In order to remain in compliance with FIFRA, an interim 24-hour reentry interval requirement must be placed on the label of all maneb end-use products registered for agricultural uses, until the required data are submitted and evaluated and any change in this reentry interval is announced.

- The Agency has screened and reviewed the environmental fate data to determine if maneb/ETU and/or its degradate(s) have the potential to leach in to ground water. The Agency has decided that a small-scale retrospective groundwater monitoring study is required to further define the extent of the ground water problem.

o While the data gaps are being filled, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing maneb as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. However, new uses will not be registered. Registrants must provide or agree to develop additional data, as specified in the Data Appendices of the Registration Standard, in order to maintain existing registrations.

6. LABELING REQUIREMENTS

All maneb products must bear appropriate labeling as specified in 40 CFR 156.10. Appendix II of the Registration Standard contains information on labeling.

The following are the major labeling specification:

- Environmental hazard statement
- Protective clothing requirements
- Preharvest interval
- Worker safety rules
- Grazing restrictions for almonds, apples, beans, corn, peanuts, potato, sugar beets, ornamental grasses, ornamental turf.

7. SUMMARY OF DATA GAPS

Product Chemistry All

Toxicology

Subchronic dermal (21-Day)
Subchronic inhalation (90-Day)
Chronic toxicity (rodent and nonrodent)
Oncogenicity (rat and mouse)
Teratology (rabbit and rat)
Reproduction (rat)
Mutagenicity (gene mutation) (other genotoxic effects)
Dermal absorption

Residue Chemistry

Nature of the Residue in Plants and Livestock
Analytical Methods
Magnitude of Residue for Variety of Commodities

Environmental Fate

Hydrolysis
Photodegradation studies in water and soil
Aerobic soil studies
Aerobic aquatic
Leaching and absorption/desorption
Aquatic (sediment)

Dissipation Soil Studies
Small-scale retrospective monitoring study
Fish accumulation

Reentry Protection

Reentry Studies on Foliar and Soil Dissipation

Wildlife and Aquatic Organisms

Avian oral toxicity
Avian dietary toxicity
Avian reproduction
Freshwater fish toxicity
Acute freshwater invertebrates
Estuarine and marine organism toxicity
Fish early life stage and invertebrate life-cycle
Aquatic organism accumulation

ETU Data Requirements

Toxicology

Chronic (rodent and non-rodent)
Reproduction

Environmental Fate

Aerobic and anaerobic soil metabolism
Aerobic aquatic
Lab volatility
Degradation (soil)
Aquatic (sediment)
Degradation (soil long-term)
Fish accumulation

8. CONTACT PERSON AT EPA

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9. DISCLAIMER: The information in this Pesticide Fact Sheet is a summary only and may not be used to satisfy data requirements for pesticide registration and reregistration. The complete Registration Standard for the pesticide may be obtained from the National Technical Information Service. Contact the Product Manager listed above for further information.